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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,052	11/22/2006	Kimihiro Mabuchi	19461-004US1 547267	2047

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EXAMINER	
CHRISTIAN, MARJORIE ELLEN	
ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
04/22/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/582,052	MABUCHI ET AL.	
	Examiner	Art Unit	
	MARJORIE CHRISTIAN	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 2/9/2009 has been entered and fully considered.

2. The objections to the information disclosure statement are withdrawn in light of Applicant's submissions.

3. Claims 1-7 are pending and have been fully considered.

Double Patenting

4. Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over:

- Claims 1-9 of copending Application No. 10/559,544; and
- Claims 1-6, 16-17 of copending Application No. 10/599,167.

Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the copending applications and the instant application disclose a hollow fiber membrane apparatus. The apparatus of the copending applications relate to hollow fiber membranes for dialysis with a hydrophobic and hydrophilic polymer that comprise at least some of the following features: the amount of hydrophilic polymer eluted, mass of hydrophilic polymer on the outer surface; and testing procedures that imply specific characteristics for hollow fiber membrane. Many of the features (various structural limitations) claimed in the instant and copending applications may not be explicitly present but are inherent or implicit. If the copending application claims an apparatus relating to hollow fiber membranes for dialysis with

some of the specific features recited above, then there is obviousness-type double patenting as it would have been obvious to one of ordinary skill in the art at the time the invention was made to have run applicant's particular recited apparatus, as taught either independently or in combination by the copending applications as selection of any of these known equivalents would be within the level of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

5. **Claims 1-2, 4-7 are rejected under 35 USC 103 (a) as being obvious over EP 0 997 182, FUKE et al. (hereinafter FUKE) in view of US Patent No. 5,071,887, NAKAGAWA et al. (hereinafter NAKAGAWA) as further evidenced by US Patent No. 6,605,218 KOZAWA et al. (hereinafter KOZAWA).**

As to Claim 1, FUKE discloses a bundle of selectively permeable polysulfone-based hollow fiber membranes (Abstract) wherein the amount of hydrophilic polymer eluted is inhibited by cross-linking using radiation (Paragraph 19, Page 4), such that the amount of water-soluble PVP becomes 5 to 50% of the total amount ***[amount of hydrophilic polymer eluting from each hollow fiber is not larger than 10ppm]***. FUKE does not explicitly disclose that the elution rate is not larger than 10 ppm however it is implicit that the elution rate can be in that range, this is further evidenced by KOZAWA. KOZAWA discloses that the amount of hydrophilic polymer eluted is not higher than 10ppm (Abstract). FUKE also discloses that the surface PVP concentration

[hydrophilic polymer] is in the range of 30% to 45% (Para. 23). FUKE does not appear to expressly disclose the UV absorbance of the test solution obtained from pieces of fiber. However, NAKAGAWA discloses a test solution obtained from pieces of fiber to a length of 2 cm, where the solution is capable of being from ten fractions of the bundle obtained at regular lengthwise intervals, absent evidence to the contrary; the test method for eluted matter is based on Approval Standard for Dialysis-type Artificial Kidney (C6/L26-27); and it is implicit that the difference between the maximum and minimum out of the maximum values of UV absorbance of the extracted solution from the fractions is not larger than 0.05, absent evidence to the contrary, and in view of the fact that is desirable to reduce the amount of elution since the absorbance of the test solution is not more than 0.1 at a wavelength of 220 nm to 350 nm, (C6/L25-52).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the polysulfone-based hollow fiber of FUKE to include the UV absorbance of the fibers in a test solution of NAKAGAWA. The motivation would have been to a have a standard test method for eluted matter (C6/L25). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

As to Claim 2, it is inherent that the hollow fiber bundle of FUKE (in view of NAKAGAWA) has *substantially no partial* sticking of the hollow fiber membranes in the lengthwise direction, absent evidence to the contrary. This is further evidenced by the fact that the partial sticking occurs when the hydrophilic polymer content is high and that FUKE reduces the amount of hydrophilic content by a washing method (Page 6, Para.

30-31, 33-34) similar to that disclosed in the instant specification (where the washing method is for the express purpose of substantially reducing the partial sticking).

As to Claim 4, FUKE (in view of NAKAGAWA) discloses that the proportion of polyvinyl pyrrolidone to polysulfone is 1 to 10% by weight, where polyvinyl pyrrolidone is the hydrophilic polymer (Claim 1) ***[mass ratio of hydrophilic polymer to polysulfone-based resin is 1 to 20 mass %]***.

As to Claims 5 and 6, FUKE (in view of NAKAGAWA) discloses that the hydrophilic polymer is poly(vinylpyrrolidone) (Abstract) and it is crosslinked by irradiation so that it is insolubilized (Page 4, Line 55).

As to Claim 7, FUKE (in view of NAKAGAWA) discloses that the hollow fiber membrane is for purifying blood (Page 3, Paragraph 11) ***[bundle is used in a blood purifier]***.

6. **Claim 3 is rejected under 35 USC 103 (a) as being obvious over EP 0 997 182, FUKE et al. (hereinafter FUKE) in view of US Patent No. 5,071,887, NAKAGAWA et al. (hereinafter NAKAGAWA) in further view of US Patent No. 5,514,413, VAN'T HOFT et al. (hereinafter VAN'T HOFT).**

As to Claim 3, FUKE (in view of NAKAGAWA) discloses a pore diameter distribution in the outer wall of the membrane (Para. 37-38). FUKE does not appear to explicitly disclose the specific range of the porosity on the outer surface. However, VAN'T HOFT discloses a surface porosity of 1 to 20% (Column 3, Lines 6-7) ***[porosity of the outer surface is 8 to 25%]***.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the porosity of the hollow fiber membrane of FUKE (in view of NAKAGAWA) to include the specific surface porosity of VAN'T HOFT. The suggestion would have been to have sufficient porosity to ensure nominal resistance to gas transport and have a polymeric substrate that meets the strength, thermal stability and process compatibility for the membrane (C3/L1-6). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

7. Applicant's arguments filed 2/9/2009 have been fully considered but they are not persuasive.

Applicant argues that because the polymer used in the hollow fiber membrane of NAKAGAWA is different from the membrane of FUKE and because of that FUKE will not meet the UV absorption requirement based on standards for artificial kidney devices. Applicant also argues that the testing methods used are different. For the purposes of clarification, NAKAGAWA is used in the 103(a) rejection of claim 1 to teach that it is well known that UV absorption is tested based on the standards for artificial kidney devices. Therefore, differences between the polymers is not relevant to what the references are teaching for the purposes of the rejection. NAKAGAWA is teaching the testing procedure. It is inherent that FUKE will meet the standards set by the testing procedure, absent persuasive evidence to the contrary. Further, it can easily be

envisaged that many hollow fiber membranes meet the testing standards for eluted matter based on standards for artificial kidney devices and numerous possible structural and operational characteristics can be envisaged for the hollow fiber membrane based on the testing method and standard for UV absorption. Therefore the testing standard does not appear to have a limiting effect on the hollow fiber membrane.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the specific type of test method from the artificial dialysis standards) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that VAN'T HOFT cannot be combined with FUKE to achieve the desired porosity on the outer surface, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Further, for the purposes of clarification, FUKE discloses that the size of the pores in each layer and the thickness of the layers influence the fractionation properties of the membrane (Para. 37-38), which are result effective variables in determining the porosity of layers (i.e. outer surface);

therefore it would be obvious to a person having ordinary skill to optimize the porosity as taught by VAN'T HOFT.

Further, it would be obvious to one of ordinary skill in the art to use the teachings of these references to arrive at applicant's invention because it produces no more than predictable results. See KSR Int'l. v. Teleflex Inc., 127 S. Ct. 1727, 1732, 82 USPQ2d 1385, 1390 (2007). "it is commonsense that familiar items have obvious uses beyond their primary purposes, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle". "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results". Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US Patent No. 5,340,480, KAWATA et al. discloses a polyvinylpyrrolidone and polysulfone membrane that meets the UV absorption standard based on the approval standards for artificial kidney apparatus (Ex. 1).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJORIE CHRISTIAN whose telephone number is (571)270-5544. The examiner can normally be reached on Monday through Thursday 7-5pm (Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MC

/Krishnan S Menon/
Primary Examiner, Art Unit 1797